

Original Contributions

A Randomized Trial Comparing Aerobic Exercise and Resistance Exercise With a Health Education Program in Older Adults With Knee Osteoarthritis

The Fitness Arthritis and Seniors Trial (FAST)

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Objective.—To determine the effects of structured exercise programs on self-reported disability in older adults with knee osteoarthritis.

Setting and Design.—A randomized, single-blind clinical trial lasting 18 months conducted at 2 academic medical centers.

Participants.—A total of 439 community-dwelling adults, aged 60 years or older, with radiographically evident knee osteoarthritis, pain, and self-reported physical disability.

Interventions.—An aerobic exercise program, a resistance exercise program, and a health education program.

Main Outcome Measures.—The primary outcome was self-reported disability score (range, 1-5). The secondary outcomes were knee pain score (range, 1-6), performance measures of physical function, x-ray score, aerobic capacity, and knee muscle strength.

Results.—A total of 365 (83%) participants completed the trial. Overall compliance with the exercise prescription was 68% in the aerobic training group and 70% in the resistance training group. Postrandomization, participants in the aerobic exercise group had a 10% lower adjusted mean (\pm SE) score on the physical disability questionnaire (1.71 ± 0.03 vs 1.90 ± 0.04 units; $P < .001$), a 12% lower score on the knee pain questionnaire (2.1 ± 0.05 vs 2.4 ± 0.05 units; $P = .001$), and performed better (mean [\pm SE]) on the 6-minute walk test (1507 ± 16 vs 1349 ± 16 ft; $P < .001$), mean (\pm SE) time to climb and descend stairs (12.7 ± 0.4 vs 13.9 ± 0.4 seconds; $P = .05$), time to lift and carry 10 pounds (9.1 ± 0.2 vs 10.0 ± 0.1 seconds; $P < .001$), and mean (\pm SE) time to get in and out of a car (8.7 ± 0.3 vs 10.6 ± 0.3 seconds; $P < .001$) than the health education group. The resistance exercise group had an 8% lower score on the physical disability questionnaire (1.74 ± 0.04 vs 1.90 ± 0.03 units; $P = .003$), 8% lower pain score (2.2 ± 0.06 vs 2.4 ± 0.05 units; $P = .02$), greater distance on the 6-minute walk (1406 ± 17 vs 1349 ± 16 ft; $P = .02$), faster times on the lifting and carrying task (9.3 ± 0.1 vs 10.0 ± 0.16 seconds; $P = .001$), and the car task (9.0 ± 0.3 vs 10.6 ± 0.3 seconds; $P = .003$) than the health education group. There were no differences in x-ray scores between either exercise group and the health education group.

Conclusions.—Older disabled persons with osteoarthritis of the knee had modest improvements in measures of disability, physical performance, and pain from participating in either an aerobic or a resistance exercise program. These data suggest that exercise should be prescribed as part of the treatment for knee osteoarthritis.

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OSTEOARTHRITIS of the knee is a common nonfatal condition and an important cause of pain and activity limitations in older people.¹⁻⁴ There are no cures or disease-modifying agents for osteoarthritis, and therefore the goals of therapy are to reduce pain and improve disability and quality of life.^{5,6}

Recently, the American College of Rheumatology published guidelines for the treatment of knee osteoarthritis that suggest that exercise should be one of the mainstays of treatment.⁵ The recommendations for exercise therapy are based on several small, short-term studies that show both aerobic and resistance exercise reduce pain and disability and improve physical fitness in people with knee osteoarthritis.⁷⁻¹⁴

See also pp 32 and 64.

Nonetheless, several questions remain unanswered about the efficacy, effectiveness, and safety of exercise for the treatment of knee osteoarthritis. First, what types of exercise are most beneficial in reducing pain and disability in people with knee osteoarthritis? Both aerobic and resistance training are recommended for treatment, but they have not been directly compared with each other. Second, will older people with knee osteoarthritis comply with long-term exercise programs? Exercise must be continued indefinitely to maintain the health benefits, yet dropout rates are high from exercise programs even among healthy older people.¹⁵ Third, what are the effects of exercise above and beyond the effects of patient education, attention, and socialization? Exercise programs improve self-efficacy and enhance social support. Are there benefits to exercise therapy beyond the

psychosocial effects? Finally, is long-term exercise harmful to people with osteoarthritis? The latter question is particularly important because abnormal stresses are thought to be important in the development of osteoarthritis, studies in animals suggest that exercise may accelerate disease progression, and there is some evidence to suggest that long-term, high-intensity exercise may lead to the development of osteoarthritis.¹⁶⁻²⁰

The Fitness and Arthritis in Seniors Trial (FAST) was undertaken to address these questions and to more clearly define the role of exercise as an intervention for knee osteoarthritis. The purpose of the trial was to determine whether 2 types of exercise (aerobic exercise and resistance exercise) improved self-reported disability, physical performance, and pain in older persons with physical disability from knee osteoarthritis over an 18-month period.

METHODS

Design

FAST was a 2-center, single-blind, randomized controlled clinical trial to compare the effects of assignment to 1 of 2 exercise interventions (aerobic exercise training and resistance exercise training) with a health education program on self-reported disability in older people with knee osteoarthritis. The secondary aims of the trial were to compare the effects of assignment to the intervention groups on measures of physical performance, knee pain, knee radiographs, aerobic capacity, and muscle strength. The study was carried out at 2 clinical centers: the University of Tennessee, Memphis, and Wake Forest University, Winston-Salem, NC. Data management and statistical analyses were performed by the Biostatistics and Data Management Core of the Claude D. Pepper Older Americans Independence Center at Wake Forest University. The study was approved by the institutional review boards of the participating institutions, and all study participants gave written informed consent to be in the study.

Participants

The eligibility criteria for participation in the study were (1) age 60 years or more; (2) pain on most days in 1 or both knees; (3) difficulty with at least 1 of the following due to knee pain: walking a quarter mile, climbing stairs, getting in and out of a car, rising from a chair, lifting and carrying groceries, getting out of bed, getting out of the bathtub, or performing shopping, cleaning, or self-care activities; and (4) radiographic evidence of knee osteoarthritis in the tibial-femoral compartment.

A potential participant was excluded if the person (1) had a medical condition that precluded safe participation in an exercise program or prevented completion of the study (myocardial infarction or stroke in the past 3 months, evidence of ischemia during the exercise treadmill test, congestive heart failure, severe chronic obstructive pulmonary disease, active treatment for cancer, insulin-dependent diabetes mellitus, hemoglobin less than 110 g/L, creatinine greater than 176.8 $\mu\text{mol/L}$ [>2.0 mg/dL], severe systemic disease, or major psychiatric disease); (2) had inflammatory arthritis (eg, rheumatoid or psoriatic); (3) exercised regularly (defined as an aerobic activity or resistance training more than 1 time per week for 20 minutes or longer); (4) planned to move from the area or be admitted to a long-term care facility within the next 2 years; (5) was unable to walk at least 420 ft in 6 minutes without a cane or assistive device; (6) was unable to walk on a treadmill without an assistive device; (7) was participating in another research study; or (8) resided in a long-term care facility. The diagnosis of a medical condition that excluded potential participants was made by a history and physical examination done by a study physician and/or laboratory testing.

Participants were recruited from the general community by mass mailings to age-eligible persons, mass media advertising, and requests to local physicians to refer their patients.

Initial screening for eligibility was done over the telephone. Those who reported knee pain and disability were invited to have a radiograph of the knee. Persons judged by a radiologist to have osteoarthritis in the tibial-femoral compartment returned for 2 additional screening visits at which eligibility was determined and baseline data were collected. At the first face-to-face screening visit the potential participants were randomly assigned either to have or not to have strength testing and exercise treadmill testing (intensive follow-up testing) at their follow-up visits. The latter was done because sample size calculations indicated only half the participants were needed to give adequate power to detect intervention effects on these 2 outcomes. Upon completion of baseline data collection, stratified, variable block randomization was used to assign eligible participants to 1 of the 3 intervention arms. The factors used for stratification were center, race (white vs African American), and assignment to intensive follow-up testing. The randomization assignment was generated by computer at the biostatistics core and sent to the clinical centers' computer at the time of randomization of the participant.

Participants were told to continue all

medications and other treatments as prescribed by their personal physicians, and participants were referred to their personal physician for all medical evaluations and care during the trial.

Interventions

Aerobic Exercise Training.—The aerobic exercise intervention consisted of a 3-month facility-based walking program and then a 15-month home-based walking program. In the former, participants met 3 times per week at a central facility in classes of 10 to 15 participants under the direct supervision of a trained exercise leader and walked on an indoor track. Following the facility-based program, participants were in a home-based exercise program that consisted of 2 phases: transition (months 4-6) and maintenance (months 7-18). During the transition phase, participants were contacted biweekly by the exercise leader, who made 4 home visits and 6 telephone calls to participants. During the home visits, the exercise leader worked with the participant to develop a walking exercise program in their home environment. Most participants chose to walk on sidewalks along streets or in nearby parks, but some walked in a nearby facility such as a gymnasium or shopping mall. During the maintenance phase, the exercise leader contacted the participant by telephone every 3 weeks during months 6 through 9 and then monthly during months 10 through 18.

Each aerobic exercise session lasted 1 hour and consisted of 3 phases: a warm-up phase (10 minutes), a stimulus phase (40 minutes), and a cool-down phase (10 minutes). The warm-up phase consisted of slow walking and 4 calisthenics: arm circles, trunk rotation, shoulder and chest stretches, and side stretch. The stimulus phase consisted of participants' walking at 50% to 70% of their heart rate reserve as determined from the screening exercise treadmill test. The cool-down consisted of slow walking and 3 flexibility exercises: a shoulder stretch, hamstring stretch, and lower back stretch. Exercise was prescribed 3 times per week.

Resistance Exercise Training.—The resistance exercise training program consisted of a 3-month facility-based program consisting of classes of 10 to 15 participants that were directed by a trained exercise leader and a 15-month home-based program with the same number of contacts as the aerobic intervention. The resistance training session lasted 1 hour and consisted of a warm-up phase (10 minutes), stimulus phase (40 minutes), and cool-down phase (10 minutes). Following 2 orientation sessions, 2 sets of 12 repetitions of the 9 exercises were performed 3 days per week for 18 months.

The 9 exercises were leg extension, leg curl, step up, heel raise, chest fly, upright row, military press, biceps curl, and a pelvic tilt. The goal was to improve the overall muscular fitness of the participant; hence, the resistance exercises were designed to strengthen major muscle groups of both the upper and lower extremities. Upper body exercises were performed with dumbbells and lower body exercises with cuff weights. Beginning with the lowest possible resistance (1.3 kg for the upper body and 1.1 kg for the lower body), weight was increased in a step-wise fashion as long as the participant could complete 2 sets of 10 repetitions. Once a plateau was reached, weight was increased after the participant performed 2 sets of 12 repetitions for 3 consecutive days. During the home-based phase, weights were exchanged at the participant's request or after a determination was made to increase the weight during the face-to-face or telephone contact.

Participants maintained exercise log books during all phases of the exercise interventions and recorded the number of prescribed exercise sessions completed and the length of each exercise session. Compliance with the exercise interventions was defined as the number of exercise sessions completed divided by the total number of sessions prescribed (3 times per week). Attendance during the center-based phase was determined through the exercise leader's records, whereas during the home-based phase attendance was calculated using information from the exercise logs. If participants did not complete their exercise logs in the home-based program, it was assumed they were not exercising.

If a participant in either of the exercise intervention groups became ill or missed exercise sessions because of injury, illness, or other reasons during the 15-month home-based period, the exercise leaders were instructed to make an extra home visit or have the participant return to the facility for a booster session and to adjust the participant's level of exercise as needed. Medical questions regarding the safety of continuing the exercise were referred to the participant's personal physician. Participants in all 3 intervention groups were provided transportation to the facility-based sessions, if they desired.

Health Education.—The health education program served as a comparison group to the 2 exercise interventions and was designed to provide attention, social interaction, and education about osteoarthritis.²¹⁻²³ Participants were assigned to groups of 10 to 15 participants. During months 1 through 3, participants received a monthly 1½-hour education session led by a trained nurse. Each session consisted

of a videotaped presentation on topics related to osteoarthritis, including physical activity and exercise, a question and answer session about the videotape or any other issues related to arthritis, and a social period of approximately 15 to 20 minutes. Preprinted educational materials from the Arthritis Foundation pertinent to each of the monthly topics were given to participants at each session. During months 4 through 6, a nurse contacted each participant biweekly by telephone and conducted a structured interview. Participants were asked about their arthritis, general health status, and any problems with medications. The participants also were given an opportunity to ask questions or voice concerns about their disease. The same telephone protocol was used during months 7 through 18, during which time the participants in the health education group were contacted monthly.

Measurements and Procedures

The trial lasted 18 months. Follow-up data were collected at 3, 9, and 18 months postrandomization. Transportation was provided to and from data collection visits for participants who requested it. Data were collected by staff who were masked to the treatment assignments.

Primary Outcome Measure

Self-report of Physical Disability.—A physical disability questionnaire was developed for use in FAST that combined 23 questions drawn from previous studies that assessed difficulty with activities of daily living.^{24,25} Participants were asked for each activity: "How much difficulty, if any, did you have over the past month doing (name of activity) because of your health or physical problem?" Subjects were asked to answer using a Likert scale from 1 (usually done with no difficulty) to 5 (unable to do). The disability questionnaire has 5 distinct activity subscales that were constructed using factor analysis: ambulation and stair climbing, transfer activities, upper extremity tasks, basic activities of daily living, and complex activities of daily living.²⁵ A composite disability score was created by averaging the scores on all 23 items. The composite index has an α reliability of 0.79.

Secondary Outcome Measures

Physical Performance Test.—We developed a physical performance test specific for patients with knee osteoarthritis and a detailed description of the physical performance test is published.²⁵ Briefly, the physical performance test consisted of (1) distance walked in 6 minutes; (2) a timed stair climb and descent; (3) a timed task that involved lifting, picking-up, and carrying a 10-pound weight; and (4) a timed task consisting

of getting in and out of a simulated car. The car task was performed only at the Wake Forest Clinical Center.

Graded Exercise Treadmill Test and Oxygen Uptake.—At baseline, all potential participants performed a symptom-limited test using a modified Naughton protocol.²⁶ A person was excluded from participation if he or she had any of the following during the treadmill test at baseline: (1) 2 mm or more of ST-segment depression at an exercise level of 4 metabolic equivalents (METs) or less, (2) hypotension, or (3) complex arrhythmias.^{26,27} During the testing, measures of ventilatory and gas exchange responses were measured on a breath-by-breath basis using a computerized system (Medical Graphics Corp, CPX System, Vadnais Heights, Minn). Oxygen uptake is reported as the volume of oxygen taken up in 1 minute per kilogram of body weight at peak exercise (peak $\dot{V}O_2$).

Strength.—Measures of isokinetic strength of knee flexion and extension muscle groups were obtained using a isokinetic dynamometer (Kin-Com 125E, Chattanooga Corp, Chattanooga, Tenn). Concentric strength of the knee extensor and knee flexor muscle groups was tested through a joint range from 90° to 30°. The results are reported as maximum torque in Newton-meters over the range of motion for concentric and knee flexion and extension at an angular velocity of 30° per second.

Knee X-rays.—Anterior-posterior standing knee x-rays were obtained at the beginning and end of the study to determine the effects of the interventions on radiographic disease. Knee x-ray films were read by a single radiologist masked both to assignment to treatment group and timing of the x-ray (whether the x-ray was obtained at the beginning or the end of the study). The classification scheme for judging the severity of osteoarthritis was adapted from Altman et al.²⁸ Both the medial and lateral compartments were graded for osteophytes, subchondral sclerosis, subchondral cysts, and loss of joint space on a 0 to 3 Likert scale using an atlas. The scores for each feature were added to compute a summary severity score ranging from 0 to 24. The results are reported as the summary score for the most severely affected knee.

Knee Pain.—The intensity of knee pain was measured using a scale developed specifically for patients with knee osteoarthritis; a detailed description of this instrument has been published.²⁹ Briefly, participants were asked to rate the intensity of knee pain during the past week on 6 activities of daily living on a Likert scale from 1 (no pain) to 6 (excruciating pain) during the 6 activities. Scores for each activity were averaged to give a

summary pain intensity score for both ambulation and transfer activities.

Demographic and Clinical Variables.—Information on age, race, education, and income were obtained by self-report from the participants. Information about comorbid conditions was obtained from self-report, medical history, medication use, and a physical examination. Hypertension was defined as self-report of hypertension and concomitant use of antihypertensive medications or an average blood pressure of 160/90 mm Hg or greater on 2 measurements. Coronary heart disease was defined as a self-report of myocardial infarction, angioplasty, coronary artery bypass surgery, or self-report of angina and use of antianginal medications. Diabetes was defined as self-reported diabetes and concomitant treatment with diet or hypoglycemic medication. Osteoarthritis in other joints was defined as a physician having told the participant that they had osteoarthritis or degenerative arthritis in the hands, spine, hips, or feet. Weight and height were measured by a standard protocol. Body mass index (BMI) was calculated as weight in kilograms divided by the square of height in meters.

Statistical Analyses

The primary objective of the trial was to compare self-reported physical disability between the health education group and the 2 exercise intervention groups. The trial was designed to randomize 133 subjects to each intervention group to achieve 100 in each group at the end of 18 months. A total sample size of 400 was projected to provide a power of 90% to detect a 20% difference in self-reported disability between the 2 exercise interventions and the health education intervention. Primary analyses were conducted by intent to treat with participants analyzed according to the initial randomized assignments. All tests of hypotheses and reported *P* values are 2-sided. Post hoc secondary analyses were performed to examine outcomes by subgroups (race, sex, age, and BMI) and by compliance with the exercise prescription.

Analysis of variance and the χ^2 test were used to test for differences in baseline characteristics by treatment group. The effects of aerobic or strengthening exercise programs on disability, performance measures of function and pain, and measures of physical fitness measured at 3, 9, and 18 months postrandomization were determined by repeated measures analysis of covariance. Analyses were conducted using SAS PROC MIXED, which analyzes all available follow-up information. Estimates of intervention effects were obtained at each follow-up observation. Tests of time of follow-up by in-

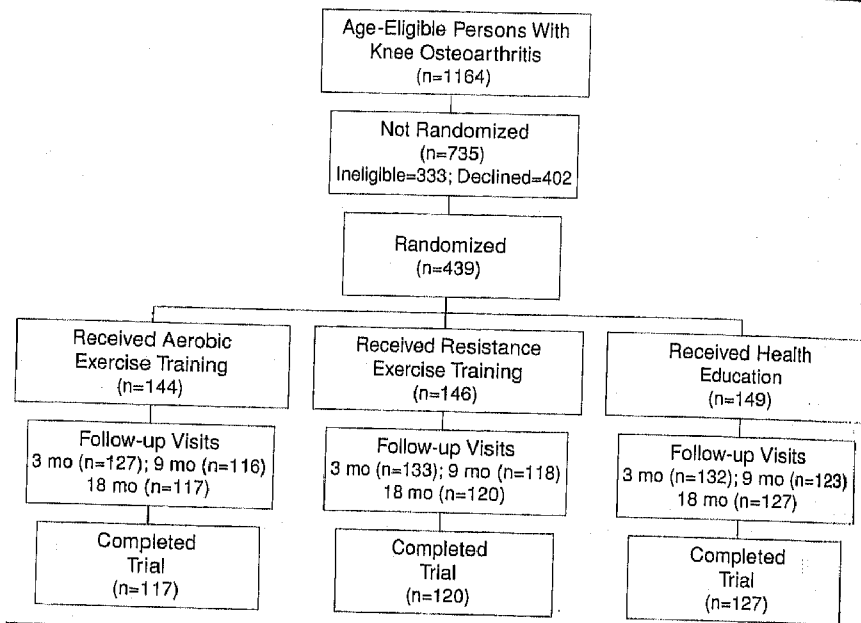


Figure 1.—Progress of participants through the trial. Reasons for ineligibility include meeting 1 or more exclusion criteria, including regular participation in exercise. Reasons for withdrawal are not known.

tervention effects were conducted to test for consistency of effects over the follow-up period. When group-by-time interactions were nonsignificant, average intervention effects over the follow-up period were estimated and tested for significance.

Analyses of group differences were adjusted for the prerandomization levels of baseline factors used in the blocked randomization to provide the correct variance estimates for the randomization design. The analyses were also adjusted for prerandomization values of other factors: self-reported disability score, physical performance score, BMI, and log peak $\dot{V}O_2$; all were significantly associated with the outcome variables after adjusting for the other terms in the model. The baseline value of the outcome of interest was also included in the analyses.

RESULTS

Recruitment of participants was conducted over a 15-month period from May 1992 to July 1993. A total of 4575 persons were screened by telephone to determine initial eligibility. Of these, 1402 (31%) had a knee x-ray; of those, 1164 (83%) were judged to have radiographically evident tibial-femoral osteoarthritis (Figure 1). Of those with radiographic knee osteoarthritis, 323 (28%) had 1 or more of the exclusion criteria, and 402 people (35%) declined to participate, leaving 439 randomized participants (38%) (208 at Wake Forest University and 231 at the University of Tennessee, Memphis). The characteristics of the randomized participants are shown in Table 1. There were no sta-

tistically significant differences among the 3 groups.

Of the 439 randomized participants, 364 (83%) completed the study (returned for the final data collection visit). Retention of participants was not significantly different among the 3 intervention groups (aerobic group, 81%, resistance group, 84%, and health education group, 88%). The study participants who dropped out were not significantly different from those who remained in terms of age, sex, race, number of chronic conditions, initial x-ray score, knee pain, or disability score.

Overall compliance with the exercise interventions was 68% for the aerobic training and 70% for the resistance training. Compliance with the exercise interventions declined over the trial: 85% at 3 months, 70% at 9 months, and 50% at 18 months. There was no statistically significant difference in compliance between the 2 exercise groups. Compliance for the health education program was 91% during the first 3 months and 95% for the remainder of the study (defined as number of scheduled follow-up calls that were successfully completed).

Six serious adverse events (death or injury possibly related to participation in the trial and requiring medical attention) occurred during the study. Of the 6 adverse events, 5 occurred in persons participating in the exercise intervention: 2 people in the aerobic group fell while walking (1 fall resulted in a fracture of the distal radius); 2 people fell during participation in the weight-training program; and 1 dropped a dumbbell on her foot resulting in a fracture. One

Table 1.—Demographic and Clinical Characteristics of the Randomized Participants in the Fitness Arthritis and Seniors Trial*

Categories	Aerobic Exercise (n=144)	Resistance Exercise (n=146)	Health Education (n=149)	P Value
Age mean±SD, y	69±6	68±6	69±6	.35
Sex, No. (%)				
Male/female	45 (31)/99 (69)	39 (27)/107 (73)	47 (31)/102 (69)	.60
Race, No. (%)				
White/African American	109 (75)/35 (24)	105 (72)/40 (28)	110 (74)/39 (26)	.66
Annual household income, \$, No. (%)				
<10 000	31 (23)	29 (21)	32 (21)	.96
10 000-19 999	40 (28)	43 (29)	41 (28)	
20 000-34 999	38 (26)	36 (25)	34 (23)	
>35 000	33 (23)	36 (25)	42 (28)	
Education, y, No. (%)				
<12	34 (24)	32 (22)	24 (16)	.32
12	31 (22)	38 (26)	32 (21)	
>12	78 (54)	76 (52)	93 (62)	
Comorbid illnesses, No. (%)				
Arthritis in other joints	103 (71.5)	112 (76.7)	107 (71.8)	.53
Obesity (BMI>30 kg/m ²)	72 (50.0)	72 (49.3)	87 (58.4)	.22
Hypertension	58 (40.3)	61 (41.8)	75 (50.3)	.17
Coronary heart disease	28 (19.4)	29 (19.9)	29 (19.5)	.99
Diabetes	10 (6.9)	14 (9.6)	16 (10.7)	.51

*Statistical comparisons of continuous means were performed using analysis of variance; comparisons of categorical variables were performed using χ^2 analysis. BMI indicates body mass index.

person in the health education group had sudden death while walking from her car to an intervention session.

Main Outcomes

The primary outcome in the trial was self-reported disability. Participants assigned to the aerobic exercise and resistance exercise intervention groups reported less disability than those in the health education group (Figure 2). On average, there was a 10% difference in adjusted mean (SE) scores (1.72 ± 0.04 vs 1.90 ± 0.04 units; $P < .001$) between the aerobic exercise group and the health education group and an 8% difference (1.74 ± 0.04 vs 1.90 ± 0.03 units; $P = .003$) between the resistance exercise and health education group. The aerobic group had significantly better scores than the health education group on the ambulation (2.22 ± 0.06 vs 2.64 ± 0.06 ; $P < .001$), transfer (1.75 ± 0.05 vs 1.92 ± 0.06 ; $P = .02$), basic activities of daily living (1.16 ± 0.03 vs 1.26 ± 0.03 ; $P = .02$) and complex activities of daily living (1.62 ± 0.05 vs 1.76 ± 0.05 ; $P = .04$) subscales. The resistance group had better scores than the health education group on the ambulation (2.37 ± 0.07 vs 2.64 ± 0.06 ; $P = .003$) and transfer (1.72 ± 0.05 vs 1.92 ± 0.06 ; $P = .005$) subscales.

The effects of assignment to the intervention groups on secondary outcomes is shown in Table 2. The aerobic exercise group walked a greater distance in 6 minutes and took less time on the stair climb, lift and carry, and car tasks than the health education group. The resistance exercise group also had significantly better scores on the per-

formance measures than the health education group on all but the stair climb task. Both exercise groups reported significantly less pain than the health education group over the course of the study. In contrast, there were no differences in x-ray scores between the exercise and health education groups. Peak $\dot{V}O_2$ was significantly increased in the aerobic exercise group compared with the health education group, but peak $\dot{V}O_2$ was not significantly different between the resistance exercise and health education groups. Both the aerobic and resistance exercise groups had significant increases in measures of strength during flexion of the knee compared with the health education group, but there were no differences in knee extension strength.

Subgroup Analyses

We performed post hoc analyses to examine whether there were differences in the effects of the interventions on disability, pain, and the 6-minute walk distance by demographic and clinical characteristics (sex, age, race, and degree of obesity) (Table 3). In general, both sexes, African Americans and whites, younger and older participants, and the very obese, who were assigned to the aerobic exercise interventions, showed improvement in self-reported disability, pain, and 6-minute walk distance compared with the health education group. Similar, significant effects on outcomes were seen in subgroups who participated in the resistance training program.

To determine if there was a dose response between compliance—percentage of prescribed exercise sessions—and ef-

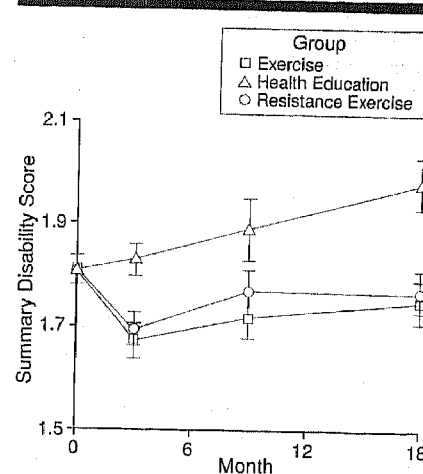


Figure 2.—Adjusted means of physical disability scores for the 3 intervention groups over the course of the study. Error bars are SE. Scores range from 1 (no difficulty) to 5 (unable to do). The aerobic exercise group had significantly lower scores, $P < .001$, over the 18-month period compared with the health education group, as did the resistance exercise group, $P = .003$. Statistical analyses were done using repeated measures analysis of covariance. The analyses of group differences were adjusted for baseline factors used in the blocked randomization (site, race, intensive follow-up) and prerandomization values of self-reported disability score, physical performance score, body mass index, and log peak $\dot{V}O_2$.

fects on outcomes, we determined the disability and pain score and 6-minute walk distance by tertile of exercise compliance (Table 4). These analyses showed that there was a significant improvement in disability, pain, and 6-minute walk distance scores with increasing compliance in both exercise groups.

COMMENT

The results of this study show that, over an 18-month period, older people with symptomatic knee osteoarthritis who participated in an aerobic or resistance exercise program had modest but consistent improvements in self-reported pain and disability and better scores on performance measures of function compared with those participating in a health education program. The beneficial effects of exercise were seen in both sexes and in several important subgroups: African Americans, obese participants, and those older than 70 years. Moreover, participants who completed more of the exercise had greater improvements in disability, pain, and performance scores. These data suggest that exercise is beneficial for a large segment of the older population with knee osteoarthritis.

The effect of exercise on measures of pain and disability in our study was modest and, in general, of a smaller magnitude than in previous studies.⁸⁻¹⁴ There are several potential reasons for the findings. First, the design of FAST may have

lessened the differences between the exercise groups and the comparison group because the latter consisted of a health education program with periodic telephone follow-ups. The health education program was designed to control for the effects of education, attention, and socialization from participation in the exercise interventions. Several studies have shown that health education is an effective intervention and can reduce pain and disability from osteoarthritis.²¹⁻²³ Moreover, the materials from the Arthritis Foundation used in the health education intervention recommended exercise as a means to cope with arthritis and may have motivated some participants to become more physically active. Thus, the differences in outcomes between the exercise and health education groups are probably less than would have occurred if the control group had received no active intervention.

Second, the modest effects of exercise on pain and disability may have been due to the relatively low intensity of both the aerobic and resistance training. In general, higher-intensity training programs lead to greater improvements in measures of fitness; however, higher-intensity exercise programs also result in increased rates of injury and lower compliance.^{15,20-32} In designing the exercise programs for FAST, we attempted to achieve balance between the intensity of the regimens with the goals of making the exercise regimens safe, simple, and acceptable to older people with physical disability. However, it is possible that a higher-intensity training program would have increased the effect of the intervention on pain and disability.

Third, the long duration of our study and the decrease in compliance with the exercise program over time probably contributed to the small differences in out-

comes between the exercise and health education groups. In support of this hypothesis, a post hoc analysis showed a direct relationship between compliance with the exercise program and benefits in terms of reduced pain and disability. The compliance rates in FAST were similar to other long-term studies of exercise in healthy older people, and these data point out the difficulty of keeping previously sedentary older adults physically active.¹⁵ Long-term compliance may be more important than the type of exercise performed in achieving the health benefits of exercise in older disabled people. For exercise to be of long-lasting benefit, it probably needs to be continued indefinitely. Better strategies need to be developed to enhance long-term compliance with exercise regimens in older adults with arthritis and other chronic illnesses.

A question for patients with knee osteoarthritis is whether participation in an exercise program accelerates the underlying disease process or results in injury. Excessive and abnormal stresses are postulated to contribute to the development of knee osteoarthritis.¹⁷ Moreover, several studies have suggested that exercise may accelerate the disease process in animals and some evidence suggests that heavy, long-term exercise may predispose a previously injured joint to knee osteoarthritis.^{16,18-20} Our results suggest that moderate exercise does not worsen the disease: we found a significant reduction in pain in the exercise groups and no change in x-ray scores. In general, the exercise was well tolerated although 2% of participants in the exercise groups had serious musculoskeletal injuries related to exercise. Thus, it appears that both moderate-intensity aerobic training and resistance training are generally safe for older people with knee

Table 2.—Comparison of Secondary Outcome Variables Between the Exercise and Health Education Interventions*

Categories	Aerobic Exercise	P Value	Resistance Exercise	P Value	Health Education
Performance measures					
6-min walk distance, ft	1507 (16)	<.001	1406 (17)	.02	1349 (16)
Stair climb, s	12.7 (0.4)	.05	13.2 (0.4)	.21	13.9 (0.4)
Lift and carry task, s	9.1 (0.2)	<.001	9.3 (0.2)	.001	10.0 (0.1)
Car task, s	8.7 (0.3)	<.001	9.0 (0.3)	.003	10.6 (0.3)
Disease activity					
Pain intensity score, 1-6	2.14 (.05)	.001	2.21 (.06)	.02	2.40 (.05)
X-ray score, 0-24	9.8 (0.3)	.70	10.0 (0.3)	.61	9.8 (0.3)
Fitness measurements					
Peak VO ₂ , mL·kg ⁻¹ ·min ⁻¹	18.3 (0.2)	.03	17.9 (0.2)	.28	17.5 (0.2)
Knee extension strength, Newton-meter at 30°	89.0 (2.0)	.44	90.2 (2.0)	.22	87.0 (1.9)
Knee flexion strength, Newton-meter at 30°	50.0 (1.1)	.004	49.5 (1.1)	.01	45.8 (1.0)

*The results are adjusted least squares mean scores with ±SEs in parentheses; statistical comparisons were made to test for the overall effects of aerobic exercise vs health education and resistance exercise vs health education using repeated measures analysis of covariance. The analyses of group differences were adjusted for baseline factors used in the blocked randomization (site, race, intensive follow-up) and prerandomization values of self-reported disability score, physical performance score, body mass index, log peak VO₂, and the outcome variable of interest.

Table 3.—Effects of Assignment to Interventions in Subgroups*

Groups	Self-reported Disability Scores					Pain Intensity Scores					6-Minute Walk Distance				
	Aerobic Exercise	P Value	Resistance Exercise	P Value	Health Education	Aerobic Exercise	P Value	Resistance Exercise	P Value	Health Education	Aerobic Exercise	P Value	Resistance Exercise	P Value	Health Education
Overall	1.72 (0.04)	<.001	1.74 (0.04)	.003	1.90 (0.04)	2.14 (0.05)	.001	2.21 (0.06)	.02	2.46 (0.05)	1507 (16)	<.001	1406 (17)	.02	1349 (16)
Sex															
Female	1.76 (0.04)	.06	1.75 (0.04)	.03	1.86 (0.04)	2.11 (0.06)	.002	2.19 (0.06)	.04	2.35 (0.06)	1512 (17)	<.001	1427 (18)	.15	1395 (18)
Male	1.64 (0.06)	<.001	1.75 (0.06)	.008	1.96 (0.06)	2.12 (0.09)	.001	2.33 (0.09)	.16	2.49 (0.09)	1468 (27)	<.001	1337 (26)	.27	1300 (26)
Age, y															
<70	1.74 (0.05)	.08	1.74 (0.04)	.09	1.84 (0.04)	2.09 (0.06)	<.001	2.22 (0.06)	.03	2.39 (0.06)	1527 (19)	<.001	1415 (18)	.14	1379 (19)
≥70	1.71 (0.05)	<.001	1.75 (0.05)	.002	1.98 (0.05)	2.15 (0.07)	.007	2.27 (0.07)	.18	2.40 (0.07)	1469 (20)	<.001	1367 (22)	.46	1345 (22)
Race															
African American	1.77 (0.07)	.08	1.65 (0.07)	.03	1.85 (0.07)	2.09 (0.10)	.05	2.19 (0.09)	.21	2.35 (0.10)	1493 (29)	<.001	1396 (29)	.07	1326 (30)
White	1.71 (0.04)	<.001	1.78 (0.04)	.01	1.91 (0.04)	2.12 (0.05)	<.001	2.25 (0.05)	.03	2.41 (0.05)	1500 (16)	<.001	1395 (17)	.41	1377 (16)
Body mass index															
Tertile 1	1.77 (0.06)	.05	1.76 (0.05)	.03	1.92 (0.06)	2.17 (0.08)	.002	2.25 (0.08)	.01	2.52 (0.07)	1532 (24)	<.001	1440 (23)	.36	1411 (26)
Tertile 2	1.69 (0.05)	.09	1.72 (0.06)	.20	1.82 (0.06)	2.13 (0.07)	.35	2.24 (0.08)	.97	2.23 (0.08)	1505 (23)	<.001	1399 (26)	.34	1367 (23)
Tertile 3	1.72 (0.06)	.002	1.96 (0.06)	.01	1.76 (0.06)	2.05 (0.08)	<.001	2.22 (0.08)	.03	2.46 (0.08)	1460 (26)	<.001	1328 (26)	.72	1315 (25)

*The results are adjusted least squares mean scores with SEs in parentheses. Statistical comparisons were made to test for effects of aerobic exercise vs health education and the resistance exercise vs health education using repeated measures analysis of covariance.

Table 4.—Effect of Compliance With Exercise Prescription on Disability, Pain, and 6-Minute Walk Distance

Compliance*	Self-reported Disability Score	Pain Intensity Score	6-Minute Walk Distance, ft
Aerobic training			
Tertile 1 (0%-39%)	2.08 (0.03)†	2.25 (0.09)‡	1461 (30)§
Tertile 2 (40%-79%)	1.88 (0.05)	2.19 (0.08)	1488 (30)
Tertile 3 (80%-100%)	1.70 (0.05)	2.08 (0.06)	1537 (24)
Resistance training			
Tertile 1 (0%-54%)	1.96 (0.06)‡	2.41 (0.09)†	1340 (59)
Tertile 2 (55%-74%)	1.95 (0.05)	2.22 (0.08)	1392 (19)
Tertile 3 (75%-100%)	1.87 (0.05)	2.18 (0.08)	1405 (19)

*Compliance is defined as the total number of exercise sessions completed divided by the number prescribed. The results are adjusted least squares mean scores with \pm SEs in parentheses, statistical comparisons made using repeated measures analysis of covariance.

† $P=0.02$.

‡ $P=0.04$.

§ $P=0.01$.

|| $P=0.05$.

osteoarthritis. However, as is true for all people who exercise, there is a small risk of serious injury from participation.³²

The cost of an intervention is an important issue in evaluating its usefulness. The total cost of an exercise prescription is the sum of the fee for a health club membership, exercise class or personal trainer, the costs of clothing, shoes, and equipment, the costs of travel to and from

a facility, and the cost of an initial medical evaluation as well as medical costs for injury or worsening of the condition. Over the long term, medical costs may be reduced if health benefits occur. The direct costs of our intervention were relatively high because of the high degree of individual attention given to participants by the exercise leaders. However, the resistance and aerobic intervention could

be carried out at a lower cost as part of a fitness class, community program, or individual home-based exercise program using self-instructional material. We do not know the long-term effect of exercise programs on medical costs in older people with knee osteoarthritis. However, regular physical activity, such as walking, is associated with reduced health care utilization in older people.³¹

In summary, our data show that exercise is a safe and effective nonpharmacological therapy that improves both pain and function in older people with knee osteoarthritis. Physicians and other health professionals should prescribe a program of moderate-intensity exercise as part of a treatment program for older people with symptomatic knee osteoarthritis.^{5,34}

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